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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,791

05/12/2005

Peter G Klimko

2444 US F

8680

Alcn Research  
Attn Teresa J Schultz  
6201 South Freeway  
Q-148  
Fort Worth, TX 76134-2099

7590

05/11/2007

EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,791	<b>Applicant(s)</b> KLIMKO ET AL.	
	<b>Examiner</b> Umamaheswari Ramachandran	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner notes the receipt of the amendments and remarks received in the office on 4/25/2007 amending claim 1. Claim 1 is pending.

The rejection of claim 1 under 35 U.S.C 102(a) is withdrawn due to the amendment of claim 1. The double patenting rejection of claim 1 is withdrawn due to the amendment of claim 1. The rejection of claim 1 under 35 U.S.C 103(a) is withdrawn due to the amendment of claim 1. Further examination and additional search necessitated the following rejections.

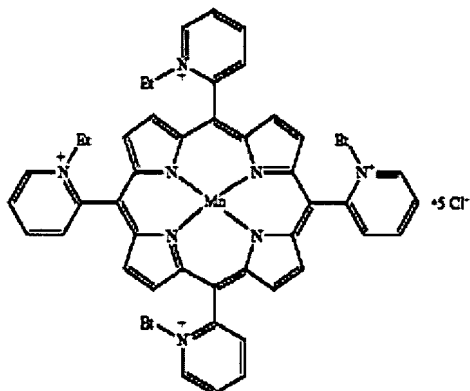
#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fridovich et al. (US 2002/0042407) in view of Kato et al. (U.S. 5,665, 769).

Fridovich et al. teach a compound of formula (I) given below (para 0020). The reference further teaches that the mimetics compounds such as formula I are useful in the treatment of diabetes mellitus I or II (para 0020, 0035). The reference further teaches the mimetics compounds can also be used for the treatment of glaucoma, and macular degeneration in the eye (para 0031).



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diabetes and another retinal disorder such as macular degeneration and one can expect similar therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fridovich et al. (WO 99/23097) in view of Kato et al. (U.S. 5,665, 769).

Fridovich et al. teach the compound of formula I (as above) (page 63, claim 16, formula I). The reference further teaches the compound to be useful in the treatment of edema, and type I and type II diabetes (page 16, lines 1-5).

The reference does not teach the compound in a method of treating diabetic retinopathy.

Kato et al.'s teachings discussed as above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a compound of formula I in a method of treatment of diabetic retinopathy because of the teachings of Fridovich and Kato et al. Fridovich teach the compound of formula I to be useful in the treatment of diabetes and edema. Kato et al. teach that macular degeneration, retinal edema and diabetic retinopathy are retinal disorders and diabetic retinopathy as one of the diabetic microangiopathy, a severe complication of diabetes. Hence one of ordinary skill in the art would have been motivated to use the compound of formula I in the treatment of diabetic retinopathy as the compound has been taught to be useful in the treatment of diabetes and another retinal disorder such as retinal edema (a type of edema) and one can expect similar

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therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Piganelli et al. (U.S. 2003/0032634) in view of Kato et al. (U.S. 5,665, 769).

Piganelli et al. teach the compound of formula I (figure 9B) shown above. The reference further teaches the compound to be useful in the prevention, delay the onset of and/or limit the severity of diabetes (p 3, para 0027). The reference also teaches that low molecular weight antioxidants can be used to treat or prevent diabetes-specific microvascular disease of, for example, the retina, renal glomerulus and peripheral nerve (e.g., resulting in oedema, ischaemia and hypoxia-induced neovascularization in the retina (para 0027).

The reference does not teach the compound in a method of treating diabetic retinopathy.

Kato et al.'s teachings discussed as above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a compound of formula I in a method of treatment of diabetic retinopathy because of the teachings of Piganelli et al. and Kato et al. Piganelli et al. teach the compound of formula I to be useful in the prevention, delay the onset of and/or limit the severity of diabetes and in the treatment or prevention of diabetes-specific microvascular disease of, for example, the retina. Kato et al. teach diabetic retinopathy as one of the diabetic microangiopathy, a severe complication of diabetes. Hence one of ordinary skill in the art would have been motivated to use the compound

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of formula I in the treatment of diabetic retinopathy as the compound has been taught to be useful in the treatment or prevention of diabetes-specific microvascular disease of, for example, the retina, and one can expect similar therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

### **Conclusion**

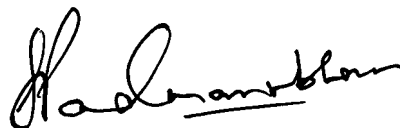
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER